

## REMARKS

Claims 1 and 27-57 are pending in the present case. Due to a restriction requirement, claims 28-32, 37-49, and 51-55 are withdrawn from consideration. In the action dated October 14, 2009, claims 1, 27, 33-36, and 56 were examined. Claims 1, 33-36, and 56 are rejected under 35 U.S.C § 102(b) as being anticipated by PCT Publication WO 97/02834 ("Dong"). Claims 1, 27, 33-36, 50, and 56 are rejected under 35 U.S.C. § 103(a) as being obvious over Dong. Each of the rejections is addressed below.

### *The Restriction Requirement*

In the Restriction Requirement mailed June 2, 2009, the Office asserted that the claims lack unity of invention over Shimizu et al., J. Biol. Chem. 276:49003-49012, 2001 ("Shimizu") on the grounds that this reference anticipates the peptide formula recited in claim 1. In the response dated August 3, 2009, Applicants amended claim 1 and traversed the unity of invention rejection. In the present action, the Office has deemed the restriction requirement proper on the grounds that the peptide of claim 1 includes at least one  $\alpha$ -helix-stabilizing residue, and that the peptide of Shimizu still reads on the present claims.

Applicants respectfully disagree. Claim 1 requires a peptide having at least one  $\alpha$ -helix-stabilizing residue, where at least one of the  $\alpha$ -helix-stabilizing residues is Ac<sub>4</sub>c or Ac<sub>6</sub>c. Thus, claim 1 requires a peptide having either an Ac<sub>4</sub>c or an Ac<sub>6</sub>c residue. Shimizu, by contrast, does not teach peptides having either of these residues and cannot anticipate claim 1 or its dependent claims. The present claims (claims 1 and 27-57) therefore possess unity of invention; the requirement for restriction is accordingly improper and should be withdrawn.

### *Rejection under 35 U.S.C. §102(b)*

Claims 1, 33-36, and 56 are rejected as being anticipated by Dong. This rejection is respectfully traversed.

For a reference to anticipate a claim, the reference must teach every element of that claim (M.P.E.P. § 2131). Claim 1 recites a formula based on the PTH(1-14) sequence having at least one  $\alpha$ -helix-stabilizing residue, where at least one of the  $\alpha$ -helix-stabilizing residues is Ac<sub>4</sub>c or Ac<sub>6</sub>c. In other words, claim 1 requires a peptide having an Ac<sub>4</sub>c or Ac<sub>6</sub>c residue. Dong does not teach peptides having either Ac<sub>4</sub>c or Ac<sub>6</sub>c and thus fails to teach this claim element. For this reason, Dong cannot anticipate claim 1 or its dependent claims. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

*Rejection under 35 U.S.C. § 103(a)*

Claims 1, 27, 33-36, 50, and 56 are rejected as being obvious over Dong. In order to find a claim obvious, “there must be some articulated reasoning with some rational underpinning to support a legal conclusion of obviousness.” *KSR v. Teleflex*, 550 U.S. 398, 418; 82 U.S.P.Q.2d 1385, 1396. Because the Office has failed to articulate a reason that would cause a person of skill in the art to arrive at the presently claimed invention on the basis of Dong, this reference cannot render the present claims obvious.

*The present claims recite PTH(1-14) peptides having an Ac<sub>4</sub>c or Ac<sub>6</sub>c substitution*

As explained above, claim 1 requires a PTH(1-14) peptide, or fragment thereof, having an  $\alpha$ -helix-stabilizing residue at at least one of positions 1, 3, 12, 13, and 14, where at least one of the  $\alpha$ -helix-stabilizing residues is Ac<sub>4</sub>c or Ac<sub>6</sub>c. Thus, the peptides of claim 1 require an Ac<sub>4</sub>c or Ac<sub>6</sub>c residue at position 1, 3, 12, 13, or 14.

Claims 27 and 50 recite a PTH(1-14) peptide having six amino acid substitutions (Ac<sub>4</sub>c<sup>1</sup>, Aib<sup>3</sup>, Gln<sup>10</sup>, Har<sup>11</sup>, Ala<sup>12</sup>, and Trp<sup>14</sup>).

*Dong does not teach the claimed peptides*

Dong does not describe the peptides of claims 1, 27, or 50. Dong instead discloses PTH(1-34) peptides having Aib, cyclohexylalanine, lysine, or other amino substitution(s)

at one or more positions, as explained at page 3, lines 12-17, and at page 7, lines 13-17. In particular, Dong does not teach peptides having an Ac<sub>4</sub>c or Ac<sub>6</sub>c substitution, PTH(1-14) peptides, or peptides having the substitutions recited in claim 27 or 50.

*The Office fails to provide a reason to make the presently claimed peptides based on Dong*

To reject the claims as being obvious over Dong, the Office must provide a reason to modify Dong's teachings to arrive at the present invention. In making this rejection, the Office asserts that substituting an  $\alpha$ -helix stabilizer in a peptide to increase binding affinities would have been obvious from Dong. This reasoning fails, as set forth below.

First, Dong does not teach that Aib substitutions increase the binding affinity of PTH peptides. Rather, Dong discloses (see Table I on page 18) that the tested peptides have binding and cAMP-activating activity. There is, however, no comparison between the tested peptides and an unsubstituted PTH peptide; nor is there any indication that these substitutions increase binding affinity or cAMP activation. Dong thus provides no reason to make  $\alpha$ -helix-stabilizing residue substitutions and additionally provides no reason to substitute Ac<sub>4</sub>c or Ac<sub>6</sub>c into PTH peptides at the positions recited in the present claims.

Dong also does not suggest making the other substitutions recited in the claims. Claim 1 recites a number of other substitutions in the PTH(1-14) sequence, and claims 27 and 50 require six substitutions (Ac<sub>4</sub>c<sup>1</sup>, Aib<sup>3</sup>, Gln<sup>10</sup>, Har<sup>11</sup>, Ala<sup>12</sup>, and Trp<sup>14</sup>) in the PTH sequence. Indeed, Dong provides no reason to make these peptides.

Finally, Dong does not suggest PTH(1-14) peptides. All of the peptides described in Dong are PTH(1-34) peptides. Because Dong does not suggest smaller PTH fragments (and certainly does not suggest N-terminal PTH fragments), Dong provides no reason to make the claimed PTH(1-14) peptides.

For all of these reasons, Dong cannot render claims 1, 27, 33-36, 50, and 56 as being obvious. Withdrawal of the rejection under 35 U.S.C. § 103(a) is accordingly requested.

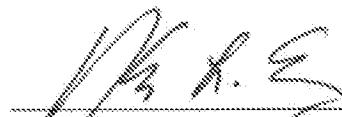
CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office action for one month, to and including February 16, 2010, as February 14, 2010 falls on a Sunday and February 15, 2010 is a Federal holiday, and payment of the required fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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